PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
Philip Jordan Thomas *et al.*

Serial No.: 10/748,720

Filed: December 30, 2003

For: PROTEIN/SOLUBILITY FOLDING ASSESSED BY STRUCTURAL COMPLEMENTATION

Group Art Unit: 1636

Examiner: P. Riggins

Atty. Dkt. No.: UTSD:703USD1/SLH

Confirmation No.: 7522

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I hereby certify that this Brief on Appeal is being electronically filed with the United States Patent and Trademark Office via EFS-Web on the date below:

April 10, 2007
Date

Steven L. Highlander

BRIEF ON APPEAL

Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

Commissioner:

This brief is submitted in response to the final Office Action mailed on September 23, 2005. The deadline for this brief is April 10, 2007, by virtue of the Notice of Appeal filed on Decemer 21, 2005, the Decision on Petition mailed October 10, 2006, and the enclosed Petition for Extension of Time (four months). The fee for this brief is enclosed herewith. Should any of appellants' fees be missing, or any other fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason relating to this document, the Commissioner is authorized to deduct said fees from Fulbright & Jaworski L.L.P. Account No.: 50-1212/UTSD:703UDS1/SLH.

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I. REAL PARTY IN INTEREST

The real party in interest of this application is the assignee, Board of Regents, University of Texas System, Austin TX.

II. RELATED APPEALS AND INTERFERENCES

There are no known related appeals or interferences.

III. STATUS OF CLAIMS

Claims 1-40 were filed with the original application. Claims 41-58 were added during prosecution and claims 1-43 were canceled. Thus, claims 44-58 are pending, stand rejected, and are appealed. A listing of the appealed claims is provided in Appendix A.

IV. STATUS OF AMENDMENTS

The status of the amendments offered after the final rejection are unknown as no Advisory Action has been received. Because appellants believe the amendments to be proper, they are included in the claims appended hereto.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent claim 44 of the application finds support in the specification at page 6, lines 15-24 and page 9, lines 6-11.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claim 44-57 are properly rejected as lacking written description for "systemic" effects.

Whether claims 44, 51, 53, and 56 are properly rejected as indefinite.

Whether claims 44, 45, 47, 52-55 and 57 are properly rejected as anticipated by Nixon (2000).

Whether claims 44, 45, 47 and 52-57 are properly rejected as anticipated by Wigley *et al.* (2001).

VII. ARGUMENT

A. Standard of Review

As an initial matter, appellant notes that findings of fact and conclusions of law by the U.S. Patent and Trademark Office must be made in accordance with the Administrative Procedure Act, 5 U.S.C. § 706(A), (E), 1994, and *Dickinson v. Zurko*, 527 U.S. 150, 158 (1999). Moreover, the Federal Circuit has held that findings of fact by the Board of Patent Appeals and Interferences must be supported by "substantial evidence" within the record. *In re Gartside*, 203 F.3d 1305, 1315 (Fed. Cir. 2000). In *In re Gartside*, the Federal Circuit stated that "the 'substantial evidence' standard asks whether a reasonable fact finder could have arrived at the agency's decision." *Id.* at 1312. Accordingly, it necessarily follows that an Examiner's position on Appeal must be supported by "substantial evidence" within the record in order to be upheld by the Board of Patent Appeals and Interferences.

B. Rejection Under 35 U.S.C. §112, First Paragraph

Claims 44-57 are rejected under §112, first paragraph, as allegedly lacking written description for "systemic" effects. The examiner correctly surmised that this is a typographical error, and appellants amended the claim to recite "systematic effects," which is indeed supported in the specification as filed - as the examiner indicated. Reversal of the rejection is therefore respectfully requested.

C. Rejections Under 35 U.S.C. §112, Second Paragraph

Claim 44 and claims depending therefrom are rejected for use of the term "systemic effects." As discussed above, appellants submit that this is a typographical error, and claim 44 has been amended to recite "systematic effects," which is agreed to be supported in the specification.

Claim 51 is rejected in reciting that luciferase is a chromophore, when it is in fact an enzyme. Appellants have dropped luciferase from this claim, adding it to claim 53 instead.

Claim 53 is rejected in reciting that cytochrome c and chymotrypsin inhibitor are enzymes. Appellants have dropped both of these terms from this claim, adding them to new claim 58 instead.

Claims 53 and 56 are rejected for the use of "and" between that last two members of the recited groups (enzymes and proteins of interest, respectively). The term "and" has been substituted with "or".

Reversal of the rejections is therefore respectfully requested.

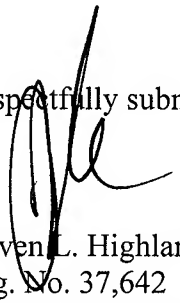
D. Rejections Under 35 U.S.C, §102

Claims 44, 45, 47, 52-55 and 57 stand rejected over Nixon (2000), and claims 44, 45, 47 and 52-57 stand rejected over Wigely *et al.* (2001). Both of these references are advanced only because of the alleged loss of priority. However, as discussed above, appellants have amended the claims to address the priority issue. Thus, neither Nixon nor Wigely *et al.* is available as prior art against the present claims. Reconsideration and withdrawal of the rejections is therefore respectfully requested.

E. Conclusion

In light of the foregoing, appellants respectfully submit that the claims are described, definite and novel over the cited references. Thus, it is requested that each of the rejections be reversed.

Respectfully submitted,



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APPENDIX A – APPEALED CLAIMS

44. A method of assessing protein folding and/or solubility comprising:

a) expressing in a host cell a fusion protein comprising (i) a protein of interest and (ii) a first segment of a marker protein, wherein said first segment has only systematic effects on the folding and/or solubility of the protein of interest;

b) contacting said fusion protein produced in step a) with a second segment of said marker protein, wherein said second segment is capable of structural complementation with said first segment; and

c) determining structural complementation,

wherein a greater degree of structural complementation, as compared to structural complementation observed with appropriate negative controls, indicates proper folding and/or solubility of said protein of interest.

45. The method of claim 44, wherein said fusion is C-terminal to said protein of interest.

46. The method of claim 44, wherein said fusion is N-terminal to said protein of interest.

47. The method of claim 44, wherein said marker protein is selected from the group consisting of a target binding protein, an enzyme, a protein inhibitor, a fluorophore and a chromophore.

48. The method of claim 47, wherein said marker protein is a target binding protein.

49. The method of claim 48, wherein said target binding protein is ubiquitin.

50. The method of claim 47, wherein said marker protein comprises a chromophore.

51. The method of claim 50, wherein said marker protein is green fluorescent protein, blue fluorescent protein, yellow fluorescent protein, or aquorin.

52. The method of claim 47, wherein said marker protein is an enzyme.

53. The method of claim 52, wherein said enzyme is β-galactosidase, luciferase, Rnase, phosphoglycerate kinase, invertase, staphylococcal nuclease, thioredoxin C, lactose permease, amino acyl tRNA synthase, or dihydrofolate reductase.

54. The method of claim 53, wherein said enzyme is β-galactosidase.

55. The method of claim 54, wherein said first segment is the α-peptide of β-galactosidase, and said second segment is the ω-peptide of β-galactosidase.

56. The method of claim 44, wherein said protein of interest is Alzheimer's amyloid peptide (Aβ), SOD1, presenilin 1 or 2, α-synuclein, amyloid A, amyloid P, CFTR, transthyretin, amylin, lysozyme, gelsolin, p53, rhodopsin, insulin, insulin receptor, fibrillin, α-ketoacid dehydrogenase, collagen, keratin, PRNP, immunoglobulin light chain, atrial natriuretic peptide, seminal vesicle exocrine protein, β2-microglobulin, PrP, precalcitonin, ataxin 1, ataxin 2, ataxin 3, ataxin 6, ataxin 7, huntingtin, androgen receptor, CREB-binding protein, dentaorubral pallidoluysian atrophy-associated protein, maltose-binding protein, ABC transporter, glutathione S transferase, or thioredoxin.

57. The method of claim 44, wherein said negative control utilizes a fusion protein that is improperly folded and/or insoluble.

58. The method of claim 47, wherein said marker protein is cytochrome C or chymotrypsin inhibitor.

APPENDIX B – EVIDENCE CITED

None

APPENDIX C – RELATED PROCEEDINGS

None